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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,193	05/29/2001	Christopher C. Adams	GP100-03.CN1	7798

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/867,193	Applicant(s) Adams
	Examiner Arun Chakrabarti	Art Unit 1655

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 21, 2002 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-18, 34, and 35 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-18, 34, and 35 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 11 and 12 are rejected under 35 U.S.C. 102 (b) as anticipated by Wright et al. (Science, (25 April, 1997), Vol. 276, pages 614-617).

Wright et al teach a purified decoy probe (Abstract and page 616, column 2, lines 6-10) comprising,

a first nucleotide base recognition sequence region, wherein the first region binds to an RNA polymerase (Figure 1 and page 615, column 1, second paragraph, lines 1-18). This rejection is based on the word "optionally". The claim language after the word "optionally" is considered as option, not an essentially required part of the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-16 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Wright et al. (Science, (25 April, 1997), Vol. 26, pages 614-617) in view of Gold et al. (U.S. Patent 5,811,533) (September 22, 1998).

Wright et al teach a purified decoy probe (Abstract and page 616, column 2, lines 6-10) comprising,

a first nucleotide base recognition sequence region, wherein the first region binds to an RNA polymerase (Figure 1 and page 615, column 1, second paragraph, lines 1-18)., and

the first region is nucleic acid which can be used to produce a functional double-stranded promoter sequence using a complementary oligonucleotide wherein the first region does not have a nucleic acid sequence greater than about 10 nucleotides in length joined directly to the 3' end of the first region (Page 615, column 3, second paragraph, lines 1-6).

Wright et al further teach the probe wherein the RNA polymerase is T7 RNA polymerase and other bacteriophage RNA polymerases (Page 615, column 1, first paragraph to column 3, second paragraph).

Wright et al further teach the probe wherein the first region has at least 35 % sequence similarity to an RNA polymerase promoter sequence (Page 615, column 3, second paragraph, lines 1 to page 616, column 1, line 4).

Wright et al further teach a reaction mixture for use in amplification reaction comprising a nucleic acid polymerase and nucleotides having a similarity to an RNA polymerase promoter sequence.

Wright et al do not teach an optionally present second nucleotide base recognition sequence region provided that the second region is either directly joined to the 5' end of the first region or is joined to the 3' end or 5' end of the first region by a non-nucleotide phosphorothioate linker.

Gold et al teach an optionally present second nucleotide base recognition sequence region provided that the second region is either directly joined to the 5' end of the first region or is joined to the 3' end or 5' end of the first region by a non-nucleotide phosphorothioate linker (Table 4 and Example 5, column 13, line 60 to column 14, line 11).

Gold et al further teach the probe wherein at least 80 % of the modified nucleosides have a purine or pyrimidine moiety independently selected from adenine, guanine and thymine and at

least 80 % of the internucleoside linkages joining the optionally modified nucleosides are phosphodiester (Table 4).

Gold et al further teach the probe wherein the probe consists 15 to 100 independently selected deoxyribonucleotides and one or more blocking groups located at the 3' terminus of the probe (Table 8).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize, within the method of Wright et al., the modified, high affinity oligonucleotide ligands of Gold et al. since Gold et al state, "This invention also includes additional post-SELEX modified RNA ligands having 2'-O-methyl groups on various purine residues. In addition, nucleotides that contain phosphorothioate backbone linkages were added at the 5' and 3' ends of the ligands in order to reduce or prevent degradation by exonucleases. Internal backbone positions were also identified in which phosphorothioate linkages could be substituted, without the loss of binding affinity, to reduce or prevent endonucleolytic degradation (Column 6, lines 25-34)". An ordinary artisan would have been motivated by the express statement of Gold et al. to combine and utilize, within the method of Wright et al., the modified, high affinity oligonucleotide ligandsof Gold et al. in order to achieve the express advantages, as noted by Gold et al. of a nucleotide system which might be used ,without the loss of binding affinity, to reduce or prevent exo as well as endonucleolytic degradation.

5. Claims 1-18 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Wright et al. (Science, (25 April, 1997), Vol. 26, pages 614-617) in view of Gold et al. (U.S. Patent

5,811,533) (September 22, 1998) further in view of Olson et al. (U.S. Patent 5,861,273) (January 19, 1999).

Wright et al. in view of Gold et al teach the probe of claims 1-16 as described above.

Wright et al. in view of Gold et al do not teach the probe wherein the first region has a nucleotide base sequence similarity of at least 75 % with at least one of SEQ ID Nos. 1-6.

Olson et al teach the probe wherein the first region has a nucleotide base sequence similarity of 100 % with SEQ ID No. 3 (Sequence No: 4, column 37).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize, within the method of Wright et al in view of Gold et al., the specific nucleotide base sequence of Olson et al. since Olson et al state, "The present invention, therefore, provides a method for producing a heterologous protein of interest (Column 3, lines 47-48)". An ordinary artisan would have been motivated by the express statement of Olson et al. to combine and utilize, within the method of Wright et al in view of Gold et al., the specific nucleotide base sequence of Olson et al. in order to achieve the express advantages, as noted by Olson et al. of a nucleotide system which provides a method for producing a heterologous protein of interest.

6. Claims 1-16, and 34-35 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Wright et al. (Science, (25 April, 1997), Vol. 26, pages 614-617) in view of Gold et al. (U.S. Patent 5,811,533) (September 22, 1998) further in view of Stackebrandt et al. (U.S. Patent 5,089,386) (February 18, 1992).

Wright et al. in view of Gold et al teach the probe of claims 1-16 as described above.

Wright et al. in view of Gold et al do not teach the purified decoy probe containing a region of self-complementarity.

Stackebrandt et al. teach the purified decoy probe containing a region of self-complementarity (Column 6, lines 32-38).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the purified decoy probe containing a region of self-complementarity of Stackebrandt et al in the method of Wright et al in view of Gold et al., since Stackebrandt et al. state, "Potentially useful target regions of the 16 S rRNA of L.Monocytogenes may be located in regions that exhibit substantial potential for self-complementarity. Therefore, probes to these regions can also exhibit self-complementarity (Column 6, lines 35-40)". An ordinary artisan would have been motivated by the express statement of Stackebrandt et al. to substitute and combine the purified decoy probe containing a region of self-complementarity of Stackebrandt et al in the method of Wright et al in view of Gold et al. in order to achieve the express advantages, as noted by Stackebrandt et al., of self complementary probes that can detect potentially useful target regions of the 16S rRNA of L.Monocytogenes located in regions that exhibit substantial potential for self-complementarity.

Response to Amendment

7. In response to amendment and terminal disclaimer, double patenting rejections are withdrawn and new 102 (b) as well as 103 (a) rejections are included.

Response to Arguments

8. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

March 1, 2002

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER